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October 18, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit To Be Assigned

Re: U.S. Utility Patent Application
Application No.: 10/773,440; Filed: February 9, 2004
For: **Method to Detect Prostate Cancer in a Sample**
Inventors: **FRADET et al.**
Our Ref: 1619.0180001/JAG/CMB

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 listing sixty-seven (67) cited documents;
3. Copies of thirty-two (32) of the cited documents; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
October 18, 2004
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The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Cynthia M. Bouchez
Attorney for Applicants
Registration No. 47,438

JAG/CMB:krh
Enclosures

319172v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Fradet *et al.*

Appl. No.: 10/773,440

Filed: February 9, 2004

For: **Method to Detect Prostate
Cancer in a Sample**

Confirmation No.: *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1619.0180001/JAG/CMB

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AK1**, **AA2-AK2**, **AA3-AK3** and **AA4-AB4** are not provided in accordance with the U.S. Patent and Trademark Office OG notice of August 5, 2003, which states "[t]he Office hereby waives the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." A copy of each other document is provided.

Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

Fradet *et al.*
Appl. No. 10/773,440

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

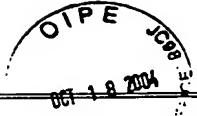
Respectfully submitted,

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Form PTO-1449 (Rev.7-80)	U.S. Department of Commerce Patent & Trademark Office	ATTY. DOCKET NO. 1619.0180001	SERIAL NO. 10/773,440
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT Fradet et al.	
		FILING DATE February 9, 2004	GROUP

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date
	AA	4,581,333	Apr. 8/86	Kourilsky et al.			
	AB	4,683,195	Jul. 28/87	Mullis et al.			
	AC	4,683,202	Jul. 28/87	Mullis			
	AD	4,786,600	Nov.22/88	Kramer et al.			
	AE	4,800,159	Jan. 24/89	Mullis et al.			
	AF	4,965,188	Oct. 23/90	Mullis et al.			
	AG	5,002,867	Mar. 26/91	Macevicz			
	AH	5,068,176	Nov. 26/91	Vijg et al.			
	AI	5,112,736	May 12/92	Caldwell et al.			
	AJ	5,118,801	June 2/92	Lizardi			
	AK	5,149,625	Sept. 22/92	Church et al.			

FOREIGN PATENT DOCUMENTS

		Document number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AL	EP 0 320 308	Mar. 11/93	EP				
	AM	EP 0 747 706	June 8/03	EP				
	AN	WO93/13121	July 8/93	WO				
	AO	WO95/32305	Nov. 30/95	WO				
	AP	WO98/02582	Jan. 22/98	WO				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	ARNOLD et al. 1989, "Assay Formats Involving Acridinium-Ester-Labeled DNA Probes", Clin. Chem. 35(8):1588-1594, Publ. by Gen-Probe, San Diego, CA
	AS	BOOM et al., Mar. 1990, "Rapid and Simple Method for Purification of Nucleic Acids", J.Clin. Microb. 28(3):495-503, Publ. by Am. Society for Microbiology
	AT	BROWN 2001, "A step-by-step guide to non-linear regression analysis of experimental data using a MS Excel spreadsheet", Comp. Methods & Programs in Biomed. 65:191-200, Publ. by Elsevier Science Ireland

Examiner	Date considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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U.S. PATENT DOCUMENTS

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	AA	5,202,231	Apr. 13/93	Dmanac et al.			
	AB	5,219,989	June 15/93	Sonenberg et al.			
	AC	5,283,174	Feb. 1/94	Arnold, Jr. et al.			
	AD	5,312,728	May 17/94	Lizardi et al.			
	AE	5,399,491	Mar. 21/95	Kacian et al.			
	AF	5,422,252	June 6/95	Walker et al.			
	AG	5,503,980	Apr. 2/96	Cantor			
	AH	5,547,842	Aug. 20/96	Hogan et al.			
	AI	5,554,516	Sept. 10/96	Kacian et al.			
	AJ	5,585,481	Dec. 17/96	Arnold, Jr. et al.			
	AK	5,639,604	June 17/97	Arnold, Jr. et al.			

FOREIGN PATENT DOCUMENTS

		Document number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AL	WO01/23550	Apr. 5/01	WO				
	AM	WO01/44507	June 21/01	WO				
	AN	WO00/50899	Aug. 31/00	WO				
	AO	WO00/58470	Oct. 5/00	WO				
	AP	WO98/45420	Oct. 15/98	WO				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	BUSSEMAKERS et al., Dec. 1, 1999, "DD3: A New Prostate-specific Gene, Highly Overexpressed in Prostate Cancer", Cancer Research 59:5975-5979, Publ. by Urology Res. Lab, Univ. Hosp. Nijmegen
	AS	DE KOK et al., May 1, 2002, "DD3 ^{PCA3} , a Very Sensitive and Specific Marker to Detect Prostate Tumors", Cancer Research 62:2695-2698, Publ. by Am. Assoc. for Cancer Res., Baltimore, MD
	AT	EDERY et al. 1988, "High-level synthesis in Escherichia coli of functional cap-binding eukaryotic initiation factor eIF-4E and affinity purifi. using a simplified cap-analog resin", Gene 74:517-52, Publ. by Elsevier

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U.S. PATENT DOCUMENTS

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	AA	5,656,207	Aug. 12/97	Woodhead et al.			
	AB	5,658,737	Aug. 19/97	Nelson et al.			
	AC	5,674,682	Oct. 7/97	Croce et al.			
	AD	5,837,832	Nov. 17/98	Chee et al.			
	AE	5,861,242	Jan. 19/99	Chee et al.			
	AF	5,925,517	Jul. 20/99	Tyagi et al.			
	AG	6,037,130	Mar. 14/00	Tyagi et al.			
	AH	6,087,133	Jul. 11/00	Dattagupta et al.			
	AI	6,110,678	Aug. 29/00	Weisburg et al.			
	AJ	6,280,952	Aug. 28/01	Weisburg et al.			
	AK	6,479,263	Nov. 12/02	Slawin et al.			

FOREIGN PATENT DOCUMENTS

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	AL							
	AM							
	AN							
	AO							
	AP							

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	GANDINI et al. 2003, "Is DD3 a New Prostate-specific Gene?", Anticancer Research 23:305-308, Publ. by Depts. Of Exp. Med & Pathology, Univ. La Sapienza, Rome, Italy
	AS	GUICHET et al., Feb. 6, 1997, "The nuclear receptor homologue Ftz-F1 and the homeodomain protein Ftz are mutually dependent cofactors", Letters to Nature 385:548-552
	AT	HESSELS et al., July 2003, "DD3 ^{PCA} -based Molecular Urine Analysis for the Diagnosis of Prostate Cancer", European Urology 44:8-16, Publ. by Elsevier

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	AA	6,534,273	Mar. 18/03	Weisburg et al.			
	AB	6,551,778	Apr. 22/03	Harvey et al.			
	AC						
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FOREIGN PATENT DOCUMENTS

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	AL							
	AM							
	AN							
	AO							
	AP							

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	KWOH et al., Feb. 1989, "Transcription-based amplification syst. and detection of amplif. human immunodef. virus type 1 with...", Proc.Natl.Acad.Sci.USA 86:1173-1177, Publ. by SIBIA, San Diego, CA
	AS	LIZARDI et al. 1988, "Exponential amplification of recombinant-RNA hybridization probes", BioTechnology 6:1197-1202
	AT	MALEK et al. 1994, "Nucleic Acid Sequence-Based Amplification (NASBA™)", Methods in Molecular Biology 28:253-260, Publ. by Hmana Press, Totowa, NJ

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	AL							
	AM							
	AN							
	AO							
	AP							

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	MATTEUCCI et al. 1981, "Synthesis of Deoxyollgonucleotides on a Polymer Support", J. Am. Chem. Soc. 103:3185-3191, Publ. by Am. Chem. Society
	AS	MILLER et al. 1988, "Oigonucleotide Inhibitors of Gene Expression in Living Cells: New Opportunities in Drug Design", Ann. Reports Med. Chem. 23:295-304, Publ. by Academic Press, Inc.
	AT	MORVAN et al. 1986, "α-DNA I. Synthesis, characterization by high field ¹ H-NMR, and base-pairing properties of the unnatural hexadeoxyribonucleotide...", Nucl Acids Res 14(12):5019-5035, IRL Press, Oxford, England

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							Yes	No
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	SCHWARTZ et al. 2001, "FTZ-Factor 1 and Fushi tarazu interact via conserved nuclear receptor and coactivator motifs", The EMBO J. 20(3):510-519
	AS	TAMIMI et al. March 1998, "DiagnoGene PCA3 reliable NASBA based reagents for detecting PCA3 mRNA, a recently described prostate marker", Proc. Am. Assoc. Cancer Res. Annual 39:234
	AT	TYAGI et al. 1995, "Molecular Beacons: Probes that Fluoresce upon Hybridization", Nature Biotechnol. 14:303-308

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	AR	VERHAEGH et al., Dec. 1, 2000, "Isolation and Characterization of the Promoter of the Human Prostate Cancer-specific DD3 Gene", J. Biol. Chem. 275(48):37496-37503, Publ. by Am Soc for Biochem & Mol Biol
	AS	WALKER et al. 1992, "Strand displacement amplification-an isothermal, in vitro DNA amplification technique", Nucl. Acids Res. 20(7):1691-1696, Publ. by Oxford University Press
	AT	WALKER et al., Jan. 1992, "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system", Proc. Natl. Acad. Sci. USA 89:392-396

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	AM							
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	AO							
	AP							

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

		WEISS Nov. 29, 1991, "Hot Prospect for New Gene Amplifier", Science 254:1292-1293
	AR	
	AS	
	AT	

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